REMARKS

Status of the Claims

Pending Claims

Claims 1, 14, 15, 33, 35, 42-45, 48, 49, 51, 54, 56, 58, 87, 106, 107, 111, 113, 116, 138, 143, 174, 175, 177, 182, 184, 187-190, 207, 208, and 215-231 are pending. Claims 42, 51, 54, 56, 58, 106, 107, 111, 113, 116, 138, 143, 174, 175, 177, 182, 184, 187, 190, 208, 215, 216, 219-224, and 229-231 are withdrawn from consideration as being drawn to a non-elected invention.

Claims canceled in the instant amendment

Claims 33, 51, 54, 56, 58, 106, 107, 215, 216 and 230 are canceled without prejudice or disclaimer. Accordingly, after entry of the instant amendment, claims 1, 14, 15, 35, 43-45, 48, 49, 87, 188-189, 207, and 217-218, and 225-228 will be pending and under examination.

Allowable Claims

Applicants thank the Examiner for noting that Claim 189 is allowed.

Outstanding Rejections

Claims 1, 14, 15, 35, 43-45, 48, 49, 87, 188, 217, 218, and 225-228 are rejected under 35 U.S.C 112, first paragraph, written description and enablement. Claim 33 is rejected under 35 U.S.C. 102(b).

Applicants respectfully traverse all outstanding rejections of the claims.

Support for the Claim Amendments

The specification sets forth an extensive description of the invention in the amended claims. Accordingly, Applicants respectfully submit that no new matter is introduced by the instant amendment.

Claim Objections

Claims 33, 218 and 225 are objected to for reasons set forth in detail on page 3 of the OA. The instant amendment addresses this issue. Therefore, the claim objections may be properly withdrawn.

Claim Rejections – 35 USC §112, first paragraph,

Written Description

Claims 1, 14, 15, 35, 43-45, 48, 49, 87, 188, 217, 218, and 225-228 are rejected under 35 U.S.C 112, first paragraph, as failing to comply with the written description requirement, as set forth in detail on pages 3-5 of the OA.

In brief, the Office rejects the claims under 35 U.S.C. § 112, first paragraph, written description requirement for allegedly not conveying to one skilled in the art that the applicant, at the time the application was filed, had possession of the large number of variant polynucleotides encoding fluorescent polypeptides. Applicants respectfully aver that the claimed invention is sufficiently described in the specification such that one of ordinary skill in the art would be able to ascertain the scope of the claims with reasonable clarity and recognize that Applicants' were in possession of the claimed invention at the time of filing.

Applicants respectfully aver that all polynucleotides of the claimed invention are described by structure (the exemplary SEQ ID NO:29), a physico-chemical property (polynucleotides having at least 95% sequence identity to SEQ ID NO:29) and function (fluorescent polypeptide activity). Applicants respectfully submit that describing a genus of polynucleotides in terms of physico-chemical properties and function satisfies the written description requirement of section 112, first paragraph, as recognized by the USPTO guidelines.

Additionally, Applicants' respectfully aver that it was not necessary for one skilled in the art to know the correlation between structure and function of fluorescent polypeptides to be in possession of the invention. One of ordinary skill in the art, using

the teaching of the specification, would have been able to make and screen for nucleic acids that encode for variants having at least 95% sequence identity to SEQ ID NO:29.

Accordingly, Applicants respectfully submit that the pending claims meet the written description requirement under 35 USC §112, first paragraph, and the rejection may be properly withdrawn

Enablement

Claims 1, 14, 15, 35, 43-45, 48, 49, 87, 188, 217, 218, and 225-228 are rejected under 35 U.S.C 112, first paragraph, as failing to comply with the enablement requirement, as set forth in detail on pages 5-9 of the OA.

The Office acknowledges that the specification is enabling for an isolated polynucleotide of SEQ ID NOS:29, and a sequence (e.g. SEQ ID NO:17) that shares 95% sequence identity to SEQ ID NO:29, both encoding fluorescent polypeptides. However, the Office alleges that the specification does not provide enablement for any isolated polynucleotide having at least 95% sequence identity with an isolated polynucleotide of SEQ ID NO:29 encoding a fluorescent polypeptide. Further, the Office alleges that the art is highly unpredictable and undue experimentation would be required to practice the claimed invention.

The Office alleges that Applicants have not provided enough guidance with regard to which regions in the protein's sequence, and the respective codons in its polynucleotide, are tolerant of modification. The Office further alleges that undue experimentation would be required of the skilled artisan to make and use the claimed invention. Applicants respectfully disagree.

It is alleged that the specification fails to provide any guidance with regard to the making of variants and mutants having 95% sequence identity to SEQ ID NO:29 and encoding a fluorescent protein. In order to make an enablement rejection, the Examiner bears the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. In re Wright, 999 F.2d 1557, 1562 (Fed. Cir. 1993). A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in

compliance with the enablement requirement of 35 USC 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained there which must be relied on for enabling support. See also MPEP §2164.04, 8th ed., rev. July 2008.

Methods of producing variants of a known sequence are well known in the art, and are also described in the specification. However, it is alleged that without sufficient guidance, the skilled artisan would be reduced to the necessity of producing and testing of variants to determine which ones have fluorescent protein activity. Applicants respectfully disagree. Procedures for identifying polypeptides having fluorescent protein activity were routine in the art at the time of the invention. Further, exemplary assays for identifying nucleic acids encoding fluorescent polypeptides are described in Example 1 of the published specification. Further, the specification provides guidance on making variants.

Additionally, whether large numbers of compositions must be screened to determine if one can be used to practice the claimed invention is irrelevant to an enablement inquiry. Enablement is not precluded by the necessity to screen large numbers of compositions, as long as that screening is routine. The Fed. Circuit in In re Wands directed that the focus of the enablement inquiry should be whether the experimentation needed to practice the invention is or is not "undue" experimentation. Guidance as to how much experimentation may be needed and still not be "undue" was set forth by the Fed. Circuit in, e.g. Hybritech, Inc. v. Monoclonal Antibodies, Inc. 802 F.2d 1367 (Fed. Cir. 1986).

The proper legal test is that the scope of enablement must only bear a "reasonable correlation" to the scope of the claims. See, e.g., In re Fisher, 427 F.2d 833, 839 (CCPA 1970). Further, the Fed. Circuit in In re Wands stated "The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." 858 F.2d 731, 737 (Fed. Cir. 1988). As the proper legal test is that the scope of enablement must only bear a reasonable correlation to the scope of the claims, methods for making the claimed genus of polynucleotides encoding fluorescent polypeptides are sufficiently enabling if a reasonable number of claimed species are successfully made by protocols known in the

art and/or described in the specification. Protocols for screening for fluorescent protein activity were well known in the art at the time of the invention, as well as described in the specification. Thus, using the teaching of the specification and other protocols known in the art at the time of the invention, one of ordinary skill in the art could have successfully practiced the invention without undue experimentation, including making and using the claimed genus of fluorescent protein encoding polynucleotides without undue experimentation.

Accordingly, the enablement rejection under section 112, first paragraph, can be properly withdrawn.

35 USC §102(b)

Claim 33 is rejected under 35 USC 102(b) as being anticipated by the Adams reference.

The instant amendment addresses these issues. Claim 33 has been canceled without prejudice or disclaimer. Therefore, Applicants respectfully request that the rejection be withdrawn.

CONCLUSION

In view of the foregoing amendment and remarks, Applicants respectfully submit that the Examiner can properly withdraw the claim objections and the rejection of pending claims under 35 U.S.C. §112, first paragraph and 35 U.S.C. §102(b). In view of the above, claims in this application after entry of the instant amendment are believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. **50-0661** referencing docket no. **D1410-2US**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: January 19, 2010

Respectfully submitted,

By /JenniferRisser/
Jennifer Risser
Registration No.:60,059
Intellectual Property Department
VERENIUM CORPORATION
PO BOX 910550
San Diego CA 92121-0550
Phone: 858-526-0376
Email: jennifer.risser@verenium.com